

CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

Submission date 19/06/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/05/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The Salford Integrated Care Programme (SICP) is a large scale project to improve care for older people with long-term conditions and social care needs in Salford. The aim of this study is to test the effectiveness of telephone health coaching for older patients (aged 65+) with multiple long-term conditions (multi-morbidity), compared to usual care.

Who can participate?

Patients aged 65+ with two or more existing long-term conditions and assessed as needing some assistance with self-management.

What does the study involve?

Patients receive a 20-minute phone call once a month for 6 months which is delivered by experienced health advisers. The health advisers and the patient agree a plan for management of their long-term conditions, including advice on healthier diet, exercise, reduction of smoking and alcohol consumption and increased social activity, as well as support for low mood (if applicable).

What are the possible benefits and risks of participating?

Previous evidence suggests that health coaching may be effective in improving outcomes, including self-management and quality of life. However, these benefits have not been confirmed for older patients with multi-morbidity in the UK NHS. The trialists are not aware of any adverse effects from health coaching

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for?

July 2014 to September 2016

Who is funding the study?

NIHR Health Services and Delivery Research (UK)

Who is the main contact?
Prof. Peter Bower
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Study website
Under construction

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16717

Study information

Scientific Title
CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS): a pragmatic, two-arm, patient-level, randomised trial of the effectiveness of telephone coaching and support for older people with multimorbidity

Acronym
CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

Study objectives
The Salford Integrated Care Programme (SICP) is a large scale transformational project to improve care for older people with long-term conditions and social care needs in Salford. SICP will deliver improved care through 3 core mechanisms:

1. Improved access to community resources and targeted support for self-management
2. Better integration of care through multidisciplinary health and social care groups providing structured, population based care.
3. An 'Integrated contact centre' to support navigation and self-management

The Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC) is an evaluation framework designed to provide a rigorous test of the ability of the SICP to deliver enhanced experience of care, improved well-being and quality of life, and reduced costs of care and improved cost effectiveness. The CLASSIC evaluation framework will adopt the cohort multiple randomised controlled trial, where a large population cohort is recruited and followed over time, with subgroups of the cohort used to evaluate the outcomes of particular SICP components.

An important component of the SICP is a contact centre providing 'health coaching'. Health coaching involves 'a regular series of phone calls between patient and health professional...to provide support and encouragement to the patient, and promote healthy behaviours such as treatment control, healthy diet, physical activity and mobility, rehabilitation, and good mental health'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. First MREC approval date 29/04/2014, ref: 14/NW/0206
2. Health Coaching Sub Project (Leeds East), approval date 26/05/2015, ref: 15/YH/0129

Study design

Both; Interventional and Observational; Design type: Process of Care, Treatment, Cohort study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care, Ageing; Subtopic: Not Assigned, Ageing; Disease: All Diseases, All Ageing

Interventions

Current interventions as of 10/03/2016:

The CLASSIC framework includes a large cohort of patients, which we will sample to recruit

patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 1306 eligible patients in the CLASSIC cohort will be randomly selected and 504 asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 802 will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

Previous interventions:

The CLASSIC framework includes a large cohort of patients, which we will sample to recruit patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 504 eligible patients in the CLASSIC cohort will be randomly selected and 50% (n=252) asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 50% will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 13/12/2016:

1. Ability to self-manage, measured using the 13-item version of the Patient Activation Measure
2. Quality of life, measured using the physical health domain of the World Health Organization Quality of Life (WHOQOL-BREF) instrument

Timepoint(s): Month 0, 20

Previous primary outcome measures from 10/03/2016 to 13/12/2016:

Health outcomes; Timepoint(s): Month 0, 6

Original primary outcome measures:

Health outcomes; Timepoint(s): Month 0, 6, 12, 18, 24

Secondary outcome measures

Current secondary outcome measures as of 13/12/2016:

1. Depression, assessed using the Mental Health Inventory-5
2. Ability to self-manage, assessed using the Summary of Diabetes Self-Care Activities (SDSCA) measure
3. Health economic analyses using the EQ5D-L measure and healthcare utilisation data

Timepoint(s): Month 0, 20

Previous secondary outcome measures from 10/03/2016 to 13/12/2016:

1. Costs; Timepoint(s): Month 0, 6
2. Patient experience; Timepoint(s): Month 0, 6

Original secondary outcome measures:

1. Costs; Timepoint(s): Month 0, 6, 12, 18, 24
2. Patient experience; Timepoint(s): Month 0, 6, 12, 18, 24

Overall study start date

14/07/2014

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Aged 65+
2. 2 or more existing long-term conditions
3. Assessed as needing some assistance with self-management (defined in terms of scores on the Patient Activation Measure)

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 504; UK Sample Size: 504; Description: Older people (65+) with long-term conditions

Key exclusion criteria

1. Patients in the palliative care stage of condition
2. Those with conditions which reduce capacity to consent and participate

Date of first enrolment

01/07/2015

Date of final enrolment

01/07/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Manchester

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Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

Health Services and Delivery Research Programme (Grant Codes: 12/130/33)

Alternative Name(s)

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Conferences, output listed in NIHR report

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2017		Yes	No
Results article	trial within a cohort results	30/05/2018		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No